

## AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application.

### LISTING OF CLAIMS

**1. (currently amended)** An extended release pharmaceutical tablet comprising:

(i) a core comprising by weight, based on the core weight, about 70% to about 99% metformin, 3 to 25% by weight of a non-hydrocolloid expanding agent, and pharmaceutically acceptable excipients; and

(ii) a coating surrounding said core, permeable to metformin, wherein the coating is free of monomeric pore forming agent,

said tablet achieving said extended release of said metformin by the design of said coating, said tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours, from about 15% to about 90% of the metformin is released; after about 8 hours, from about 50% to about 100% of the metformin is released; after about 12 hours, more than about 75% of the metformin is released.

**2. (previously presented)** The extended release pharmaceutical tablet of claim 1 wherein the coating comprises a water-insoluble, water-permeable film-forming polymer; a water-soluble polymer and a plasticizer.

**3. (cancelled)**

**4. (previously presented)** The extended release pharmaceutical tablet of claim 2 wherein the metformin is a pharmaceutically acceptable salt.

**5. (previously presented)** The extended release pharmaceutical tablet of claim 4 wherein the metformin is metformin hydrochloride.

**6. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose.

**7. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-soluble polymer is selected from the group consisting of cellulose ethers, vinylic polymers and combinations thereof.

**8. (original)** The extended release pharmaceutical tablet of claim 7 wherein the cellulose ethers is selected from the group consisting of methylcellulose, hydroxymethylcellulose, non-ionic cellulose ethers and combinations thereof.

**9. (original)** The extended release pharmaceutical tablet of claim 8 wherein the non-ionic cellulose ethers is selected from the group consisting of hydroxypropylcellulose, hydroxyethylcellulose and combinations thereof.

**10. (original)** The extended release pharmaceutical tablet of claim 7 wherein the vinylic polymers is selected from the group consisting of polyvinyl alcohol, polyvinylpyrrolidone and combinations thereof.

**11. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-soluble polymer is also alcohol-soluble.

**12. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-soluble polymer is also soluble in mixtures of alcohol and water.

**13. (original)** The extended release pharmaceutical tablet of claim 11 wherein the water-soluble polymer which is also alcohol-soluble is selected from the group consisting of hydroxypropylcellulose, polyvinylpyrrolidone and combinations thereof.

**14. (original)** The extended release pharmaceutical tablet of claim 13 wherein the water-soluble polymer which is also alcohol-soluble is polyvinylpyrrolidone.

**15. (original)** The extended release pharmaceutical tablet of claim 12 wherein the water-soluble polymer which is also soluble in mixtures of alcohol and water is hydroxypropylmethylcellulose.

**16. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-soluble polymer is polyvinylpyrrolidone.

**17. (original)** The extended release pharmaceutical tablet of claim 2 wherein the plasticizer is selected from the group consisting of stearic acid and dibutyl sebacate.

**18. (original)** The extended release pharmaceutical tablet of claim 17 wherein the plasticizer is stearic acid.

**19. (original)** The extended release pharmaceutical tablet of claim 17 wherein the plasticizer is dibutyl sebacate.

**20. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is stearic acid.

**21. (original)** The extended release pharmaceutical tablet of claim 2 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is dibutyl sebacate.

**22.-24. (cancelled)**

**25. (currently amended)** The extended release pharmaceutical tablet of ~~claim 24~~ claim 1 wherein the non-hydrocolloid is crospovidone.

**26. (cancelled)**

**27. (currently amended)** The extended release pharmaceutical tablet of ~~claim 23~~ claim 1 wherein the weight ratio of water-insoluble, water-permeable film-forming polymer: water-soluble polymer: plasticizer is 20-50:35-75:15-40.

**28. (original)** The extended release pharmaceutical tablet of claim 1 wherein the pharmaceutically acceptable excipients comprise glyceryl behenate, polyvinylalcohol and silicon dioxide.

**29. (original)** The extended release pharmaceutical tablet of claim 1 exhibiting a dissolution profile such that after about 2 hours from about 10% to about 40% of the metformin is released; after about 4 hours from about 20% to about 65% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released and after about 12 hours more than about 75% of the metformin is released.

**30. (original)** The extended release pharmaceutical tablet of claim 1 exhibiting a dissolution profile such that after about 2 hours from about 40 % to about 60% of the metformin is released; after about 4 hours from about 65% to about 90% of the metformin is released; after about 8 hours from about 85% to about 100% of the metformin is released and after about 12 hours more than about 90% of the metformin is released.

**31. (currently amended)** An extended release pharmaceutical tablet comprising:  
(i) a core comprising by weight, based on the core weight, about 70% to about 99% metformin, 3 to 25% by weight of a non-hydrocolloid expanding agent, and conventional excipients; and

(ii) a coating surrounding said core, wherein said coating is permeable to metformin, said coat comprising by weight, based on the coating weight, of about 20% to about 85% of a water-insoluble, water-permeable film-forming polymer, of about 10% to about 75% of a water soluble polymer and about 3% to about 40% of a plasticizer, wherein the coating is free of monomeric pore forming agent,

said tablet achieving said extended release of said metformin by the design of said coating, the tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours, from about 15% to about 90% of the metformin is released; after about 8 hours, from about 50% to about 100% of the metformin is released; after about 12 hours, more than about 75% of the metformin is released.

**32. (cancelled)**

**33. (previously presented)** The extended release pharmaceutical tablet of claim 31 wherein the metformin is a pharmaceutically acceptable salt.

**34. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose.

**35. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-soluble polymer is selected from the group consisting of cellulose ethers, vinylic polymers and combinations thereof.

**36. (original)** The extended release pharmaceutical tablet of claim 35 wherein the cellulose ethers is selected from the group consisting of methylcellulose, hydroxymethylcellulose, non-ionic cellulose ethers and combinations thereof.

**37. (original)** The extended release pharmaceutical tablet of claim 36 wherein the non-ionic cellulose ethers is selected from the group consisting of hydroxypropylcellulose, hydroxyethylcellulose and combinations thereof.

**38. (original)** The extended release pharmaceutical tablet of claim 35 wherein the vinyl polymers is selected from the group consisting of polyvinyl alcohol, polyvinylpyrrolidone and combinations thereof.

**39. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-soluble polymer is also alcohol-soluble.

**40. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-soluble polymer is also soluble in mixtures of alcohol and water.

**41. (original)** The extended release pharmaceutical tablet of claim 39 wherein the water-soluble polymer which is also alcohol-soluble is selected from the group consisting of hydroxypropylcellulose, polyvinylpyrrolidone and combinations thereof.

**42. (original)** The extended release pharmaceutical tablet of claim 41 wherein the water-soluble polymer which is also alcohol-soluble is polyvinylpyrrolidone.

**43. (original)** The extended release pharmaceutical tablet of claim 40 wherein the water-soluble polymer which is also soluble in mixtures of alcohol and water is hydroxypropylmethylcellulose.

**44. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-soluble polymer is polyvinylpyrrolidone.

**45. (previously presented)** The extended release pharmaceutical tablet of claim 31 wherein the metformin is metformin hydrochloride.

**46. (original)** The extended release pharmaceutical tablet of claim 45 wherein the plasticizer is stearic acid.

**47. (original)** The extended release pharmaceutical tablet of claim 45 wherein the plasticizer is dibutyl sebacate.

**48. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is stearic acid.

**49. (original)** The extended release pharmaceutical tablet of claim 31 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is dibutyl sebacate.

**50.-52. (cancelled)**

**53. (currently amended)** The extended release pharmaceutical tablet of ~~claim 52~~ claim 31 wherein the non-hydrocolloid is crospovidone.

**54. (cancelled)**

**55. (currently amended)** The extended release pharmaceutical tablet of ~~claim 51~~ claim 31 wherein the weight ratio of water-insoluble, water-permeable film-forming polymer: water-soluble polymer: plasticizer is 20-50:35-75:15-40.

**56. (original)** The extended release pharmaceutical tablet of claim 31 wherein the pharmaceutically acceptable excipients comprise glyceryl behenate, polyvinylalcohol and silicon dioxide.

**57. (original)** The extended release pharmaceutical tablet of claim 31 exhibiting a dissolution profile such that after about 2 hours from about 10% to about 40% of the metformin is released; after about 4 hours from about 20% to about 65% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released and after about 12 hours more than about 75% of the metformin is released.

**58. (original)** The extended release pharmaceutical tablet of claim 31 exhibiting a dissolution profile such that after about 2 hours from about 40 % to about 60% of the metformin is released; after about 4 hours from about 65% to about 90% of the metformin is released; after about 8 hours from about 85% to about 100% of the metformin is released and after about 12 hours more than about 90% of the metformin is released.

**59. (currently amended)** An extended release extended release pharmaceutical tablet comprising:

(i) a core comprising by weight, based on the core weight, about 70% to about 99% metformin, 3 to 25% by weight of a non-hydrocolloid expanding agent, and pharmaceutically acceptable excipients; and

(ii) a coating surrounding said core, wherein said coating is permeable to metformin, said coat comprising by weight, based on the coating weight, from about 50% to about 85% of a water-insoluble, water-permeable film-forming polymer, from about 10% to about 35% of a water soluble polymer and from about 3% to about 15% of a plasticizer, wherein the coating is free of monomeric pore forming agent,

said tablet achieving said extended release of said metformin by the design of the coating, the tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours, from about 15% to about 90% of the metformin is released; after about 8 hours, from about 50% to about 100% of the metformin is released; after about 12 hours, more than about 75% of the metformin is released.

**60. (cancelled)**

**61. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose.

**62. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-soluble polymer is selected from the group consisting of cellulose ethers, vinylic polymers and combinations thereof.

**63. (original)** The extended release pharmaceutical tablet of claim 62 wherein the cellulose ethers is selected from the group consisting of methylcellulose, hydroxymethylcellulose, non-ionic cellulose ethers and combinations thereof.

**64. (original)** The extended release pharmaceutical tablet of claim 63 wherein the non-ionic cellulose ethers is selected from the group consisting of hydroxypropylcellulose, hydroxyethylcellulose and combinations thereof.

**65. (original)** The extended release pharmaceutical tablet of claim 62 wherein the vinylic polymers is selected from the group consisting of polyvinyl alcohol, polyvinylpyrrolidone and combinations thereof.

**66. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-soluble polymer is also alcohol-soluble.

**67. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-soluble polymer is also soluble in mixtures of alcohol and water.

**68. (original)** The extended release pharmaceutical tablet of claim 66 wherein the water-soluble polymer which is also alcohol-soluble is selected from the group consisting of hydroxypropylcellulose, polyvinylpyrrolidone and combinations thereof.

**69. (original)** The extended release pharmaceutical tablet of claim 68 wherein the water-soluble polymer which is also alcohol-soluble is polyvinylpyrrolidone.

**70. (original)** The extended release pharmaceutical tablet of claim 67 wherein the water-soluble polymer which is also soluble in mixtures of alcohol and water is hydroxypropylmethylcellulose.

**71. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-soluble polymer is polyvinylpyrrolidone.

**72. (previously presented)** The extended release pharmaceutical tablet of claim 59 wherein the metformin is metformin hydrochloride.

**73. (previously presented)** The extended release pharmaceutical tablet of claim 59, wherein the plasticizer is stearic acid.

**74. (previously presented)** The extended release pharmaceutical tablet of claim 59, wherein the plasticizer is dibutyl sebacate.

**75. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is stearic acid.

**76. (original)** The extended release pharmaceutical tablet of claim 59 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is dibutyl sebacate.

**77.-79. (cancelled)**

**80. (currently amended)** The extended release pharmaceutical tablet of ~~claim 79~~ claim 59 wherein the non-hydrocolloid expanding agent is crospovidone.

**81. (cancelled)**

**82. (original)** The extended release pharmaceutical tablet of claim 59 wherein the pharmaceutical excipients comprise glyceryl behenate, polyvinylalcohol and silicon dioxide.

**83. (original)** The extended release pharmaceutical tablet of claim 59 exhibiting a dissolution profile such that after about 2 hours from about 10% to about 40% of the metformin is released; after about 4 hours from about 20% to about 65% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released and after about 12 hours more than about 75% of the metformin is released.

**84. (original)** The extended release pharmaceutical tablet of claim 59 exhibiting a dissolution profile such that after about 2 hours from about 40 % to about 60% of the metformin is released; after about 4 hours from about 65% to about 90% of the metformin is released; after about 8 hours from about 85% to about 100% of the metformin is released and after about 12 hours more than about 90% of the metformin is released.

**85. (currently amended)** An extended release tablet comprising:

(i) a core comprising by weight, based on the core weight, 70 to 99% of metformin, 3 to 25% by weight of a non-hydrocolloid an-expanding agent and pharmaceutically acceptable excipients; and

(ii) a coating surrounding said core, wherein said coating is permeable to metformin, and wherein the coating is free of monomeric pore forming agent, said coat comprising by weight, based on the coating weight, from about 20% to about 50% of a water-insoluble, water-permeable film-forming polymer, from about 35% to about 75% of a water-soluble polymer and from about 15% to about 40% of a plasticizer;

said tablet achieving said extended release of said metformin by the design of said coating, the tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours from about 15% to about 90% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released; and after about 12 hours, more than about 75% of the metformin is released.

**86. (cancelled)**

**87. (original)** The extended release tablet of claim **85** wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose.

**88. (original)** The extended release pharmaceutical tablet of claim **85** wherein the water-soluble polymer is selected from the group consisting of cellulose ethers, vinylic polymers and combinations thereof.

**89. (original)** The extended release pharmaceutical tablet of claim **88** wherein the cellulose ethers is selected from the group consisting of methylcellulose, hydroxymethylcellulose, non-ionic cellulose ethers and combinations thereof.

**90. (original)** The extended release pharmaceutical tablet of claim **89** wherein the non-ionic cellulose ethers is selected from the group consisting of hydroxypropylcellulose, hydroxyethylcellulose and combinations thereof.

**91. (previously presented)** The extended release pharmaceutical tablet of claim **88** wherein the vinylic polymers is selected from the group consisting of polyvinyl alcohol, polyvinylpyrrolidone and combinations thereof.

**92. (previously presented)** The extended release pharmaceutical tablet of claim **85** wherein the water-soluble polymer is also alcohol-soluble.

**93. (previously presented)** The extended release pharmaceutical tablet of claim **85** wherein the water-soluble polymer is also soluble in mixtures of alcohol and water.

**94. (previously presented)** The extended release pharmaceutical tablet of claim **92** wherein the water-soluble polymer which is also alcohol-soluble is selected from the group consisting of hydroxypropylcellulose, polyvinylpyrrolidone and combinations thereof.

**95. (previously presented)** The extended release pharmaceutical tablet of claim 94 wherein the water-soluble polymer which is also alcohol-soluble is polyvinylpyrrolidone.

**96. (previously presented)** The extended release pharmaceutical tablet of claim 93 wherein the water-soluble polymer which is also soluble in mixtures of alcohol and water is hydroxypropylmethylcellulose.

**97. (previously presented)** The extended release tablet of claim 85 wherein the water-soluble polymer is polyvinylpyrrolidone.

**98. (previously presented)** The extended release pharmaceutical tablet of claim 85 wherein the plasticizer is selected from the group consisting of stearic acid and dibutyl sebacate.

**99. (previously presented)** The extended release pharmaceutical tablet of claim 98 wherein the plasticizer is stearic acid.

**100. (previously presented)** The extended release pharmaceutical tablet of claim 98 wherein the plasticizer is dibutyl sebacate.

**101. (previously presented)** The extended release pharmaceutical tablet of claim 85 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is stearic acid.

**102. (previously presented)** The extended release pharmaceutical tablet of claim 85 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is dibutyl sebacate.

**103.-104. (cancelled)**

**105. (currently amended)** The extended release pharmaceutical tablet of ~~claim 104~~ claim 85 wherein the non-hydrocolloid is crospovidone.

**106. (cancelled)**

**107. (previously presented)** The extended release pharmaceutical tablet of claim 85 wherein the pharmaceutically acceptable excipients comprises glyceryl behenate, polyvinylalcohol and silicon dioxide.

**108. (previously presented)** The extended release pharmaceutical tablet of claim 85 exhibiting a dissolution profile such that after about 2 hours from about 10% to about 40% of the metformin is released; after about 4 hours from about 20% to about 65% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released and after about 12 hours more than about 75% of the metformin is released.

**109. (previously presented)** The extended release pharmaceutical tablet of claim 85 exhibiting a dissolution profile such that after about 2 hours from about 40 % to about 60% of the metformin is released; after about 4 hours from about 65% to about 90% of the metformin is released; after about 8 hours from about 85% to about 100% of the metformin is released and after about 12 hours more than about 90% of the metformin is released.

**110. -113. (cancelled)**

**114. (previously presented)** An extended release pharmaceutical tablet comprising:

- (i) a core comprising by weight, based on the core weight, 70 to 99% of metformin or a pharmaceutically acceptable salt of metformin, crospovidone, glyceryl behenate, polyvinyl alcohol, silicon dioxide; and
- (ii) a coating surrounding said core, wherein said coating is permeable to metformin and free of monomeric pore forming agent, said coat comprising by weight, based on the coating weight, from about 20% to about 50% of a water-insoluble, water-permeable film-forming polymer, from about 35% to about 75% of a water-soluble polymer and from about 15% to about 40% of a plasticizer;

said tablet achieving said extended release of said metformin by the design of the coating, said tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours from about 15% to about 90% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released; and after about 12 hours, more than about 75% of the metformin is released.

**115. (previously presented)** The extended release pharmaceutical tablet of claim -114 wherein the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is selected from the group consisting of stearic acid and dibutyl sebacate.

**116. (previously presented)** An extended release pharmaceutical tablet comprising:

(i) a core comprising by weight, based on the core weight, 70 to 99% of metformin or a pharmaceutically acceptable salt of metformin, crospovidone, glyceryl behenate, polyvinyl alcohol, silicon dioxide; and

(ii) a coating surrounding said core, wherein said coating is permeable to metformin and free of monomeric pore forming agent, said coating comprising by weight, based on the coating weight, from about 20% to about 50% of ethylcellulose, from about 35% to about 75% of polyvinylpyrrolidone and from about 15% to about 40% of stearic acid;

said tablet achieving said extended release of said metformin by the design of the coating, said tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours from about 15% to about 90% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released; and after about 12 hours, more than about 75% of the metformin is released.

**117. (previously presented)** An extended release pharmaceutical tablet comprising:

(i) a core comprising by weight, based on the core weight, 70 to 99% of metformin or a pharmaceutically acceptable salt of metformin, crospovidone, glyceryl behenate, polyvinyl alcohol, and silicon dioxide; and

(ii) a coating surrounding said core, wherein said coating is permeable to metformin and free of monomeric pore forming agent, said coat comprising by weight, based on the coating weight, from about 20% to about 50% of ethylcellulose, from about 35% to about 75% of polyvinylpyrrolidone and from about 15% to about 40% of dibutyl sebacate ;

said tablet achieving said extended release of said metformin by the design of the coating, said tablet exhibiting a dissolution profile such that after about 2 hours, from about 7% to about 60% of the metformin is released; after about 4 hours from about 15% to about 90% of the metformin is released; after about 8 hours from about 50% to about 100% of the metformin is released; and after about 12 hours, more than about 75% of the metformin is released.

**118. (previously presented)** An extended release pharmaceutical tablet comprising:

- (i) a core comprising per coated tablet weight about 86% metformin hydrochloride, about 2% colloidal silicon dioxide, about 3% polyvinyl alcohol, about 3.5% crospovidone and about 2% glyceryl behenate; and
- (ii) a coating surrounding said core, wherein said coating is permeable to metformin hydrochloride, said coat comprising per coated tablet weight about 2% ethylcellulose, about 1% polyvinylpyrrolidone and about 0.5% dibutyl sebacate.

**119. (previously presented)** An extended release pharmaceutical tablet comprising:

- (i) a core comprising by weight per coated tablet weight about 1000 mg metformin hydrochloride, about 25 mg colloidal silicon dioxide, about 34 mg polyvinylalcohol, about 39 mg crospovidone and about 22 mg glyceryl behenate; and
- (ii) a coat surrounding said core, wherein said coat is permeable to metformin hydrochloride, said coat comprising by weight per coated tablet weight about 21 mg ethyl cellulose, about 11 mg polyvinylpyrrolidone, and about 8 mg dibutyl sebacate

**120. (previously presented)** An extended release pharmaceutical tablet comprising:

- (i) a core comprising by weight per coated tablet weight about 750 mg metformin hydrochloride, about 19 mg colloidal silicon dioxide, about 26 mg polyvinylalcohol, about 30 mg crospovidone and about 17 mg glyceryl behenate; and
- (ii) a coat surrounding said core, wherein said coat is permeable to metformin hydrochloride, said coat comprising by weight per coated tablet weight about 21 mg ethylcellulose, 11 mg polyvinylpyrrolidone and about 8 mg dibutyl sebacate.